

ASSEMBLY BILL

No. 1069

Introduced by Assembly Member Gordon

February 26, 2015

An act to amend Section 150204 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 1069, as introduced, Gordon. Prescription drugs: collection and distribution program.

Existing law authorizes a county to establish a repository and distribution program under which a pharmacy, including a that is owned by, or contracts with, the county, may distribute surplus unused medications, as defined, to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. Under existing law, only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet the United States Pharmacopoeia standards is eligible for donation to the program. Existing law also prohibits the donation of controlled substances to the repository and distribution program. Existing law prohibits medication that does not meet the requirements for donation and distribution from being sold, dispensed, or otherwise transferred to any other entity.

This bill would make a technical, nonsubstantive change to these provisions.

Vote: majority. Appropriation: no. Fiscal committee: no.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 150204 of the Health and Safety Code
2 is amended to read:

3 150204. (a) (1) A county may establish, by an action of the
4 county board of supervisors or by an action of the public health
5 officer of the county, as directed by the county board of
6 supervisors, a repository and distribution program for purposes of
7 this division. The county shall advise the California State Board
8 of Pharmacy within 30 days from the date it establishes a repository
9 and distribution program.

10 (2) Only an eligible entity, pursuant to subdivision (a) of Section
11 150201, may participate in this program to dispense medication
12 donated to the drug repository and distribution program.

13 (3) An eligible entity that seeks to participate in the program
14 shall inform the county health department and the California State
15 Board of Pharmacy in writing of its intent to participate in the
16 program. An eligible entity may not participate in the program
17 until it has received written or electronic documentation from the
18 county health department confirming that the department has
19 received its notice of intent.

20 (4) (A) A participating entity shall disclose to the county health
21 department on a quarterly basis the name and location of the source
22 of all donated medication it receives.

23 (B) A participating primary care clinic, as described in paragraph
24 (3) of subdivision (a) of Section 150201 shall disclose to the county
25 health department the name of the licensed physician who shall
26 be accountable to the California State Board of Pharmacy for the
27 clinic's program operations pursuant to this division. This physician
28 shall be the professional director, as defined in subdivision (c) of
29 Section 4182 of the Business and Professions Code.

30 (C) The county board of supervisors or public health officer of
31 the county shall, upon request, make available to the California
32 State Board of Pharmacy the information in this division.

33 (5) The county board of supervisors, the public health officer
34 of the county, and the California State Board of Pharmacy may
35 prohibit an eligible or participating entity from participating in the
36 program if the entity does not comply with the provisions of the
37 program, pursuant to this division. If the county board of
38 supervisors, the public health officer of the county, or the California

1 State Board of Pharmacy prohibits an eligible or participating
2 entity from participating in the program, it shall provide written
3 notice to the prohibited entity within 15 days of making this
4 determination. The county board of supervisors, the public health
5 officer of the county, and the California State Board of Pharmacy
6 shall ensure that this notice also is provided to one another.

7 (b) A county that elects to establish a repository and distribution
8 program pursuant to this division shall establish written procedures
9 for, at a minimum, all of the following:

10 (1) Establishing eligibility for medically indigent patients who
11 may participate in the program.

12 (2) Ensuring that patients eligible for the program shall not be
13 charged for any medications provided under the program.

14 (3) Developing a formulary of medications appropriate for the
15 repository and distribution program.

16 (4) Ensuring proper safety and management of any medications
17 collected by and maintained under the authority of a participating
18 entity.

19 (5) Ensuring the privacy of individuals for whom the medication
20 was originally prescribed.

21 (c) Any medication donated to the repository and distribution
22 program shall comply with the requirements specified in this
23 division. Medication donated to the repository and distribution
24 program shall meet all of the following criteria:

25 (1) The medication shall not be a controlled substance.

26 (2) The medication shall not have been adulterated, misbranded,
27 or stored under conditions contrary to standards set by the United
28 States Pharmacopoeia (USP) or the product manufacturer.

29 (3) The medication shall not have been in the possession of a
30 patient or any individual member of the public, and in the case of
31 medications donated by a health or care facility, as described in
32 Section 150202, shall have been under the control of a staff
33 member of the health or care facility who is licensed in California
34 as a health care professional or has completed, at a minimum, the
35 training requirements specified in Section 1569.69.

36 (d) (1) Only medication that is donated in unopened,
37 tamper-evident packaging or modified unit dose containers that
38 meet USP standards is eligible for donation to the repository and
39 distribution program, provided lot numbers and expiration dates
40 are affixed. Medication donated in opened containers shall not be

1 dispensed by the repository and distribution program, and once
2 identified, shall be quarantined immediately and handled and
3 disposed of in accordance with the Medical Waste Management
4 Act (Part 14 (commencing with Section 117600) of Division 104).

5 (2) (A) A medication that is the subject of a United States Food
6 and Drug Administration managed risk evaluation and mitigation
7 strategy pursuant to Section 355-1 of Title 21 of the United States
8 Code shall not be donated if this inventory transfer is prohibited
9 by that strategy, or if the inventory transfer requires prior
10 authorization from the manufacturer of the medication.

11 (B) A medication that is the subject of a United States Food and
12 Drug Administration managed risk evaluation and mitigation
13 strategy pursuant to Section 355-1 of Title 21 of the United States
14 Code, the donation of which is not prohibited pursuant to
15 subparagraph (A), shall be managed and dispensed according to
16 the requirements of that strategy.

17 (e) A pharmacist or physician at a participating entity shall use
18 his or her professional judgment in determining whether donated
19 medication meets the standards of this division before accepting
20 or dispensing any medication under the repository and distribution
21 program.

22 (f) A pharmacist or physician shall adhere to standard pharmacy
23 practices, as required by state and federal law, when dispensing
24 all medications.

25 (g) Medication that is donated to the repository and distribution
26 program shall be handled in the following ways:

27 (1) Dispensed to an eligible patient.

28 (2) Destroyed.

29 (3) Returned to a reverse distributor or licensed waste hauler.

30 (4) (A) Transferred to another participating entity within the
31 county to be dispensed to eligible patients pursuant to this division.
32 Notwithstanding this paragraph, a participating county-owned
33 pharmacy may transfer eligible donated medication to a
34 participating county-owned pharmacy within another adjacent
35 county that has adopted a program pursuant to this division, if the
36 pharmacies transferring the medication have a written agreement
37 between the entities that outlines protocols and procedures for safe
38 and appropriate drug transfer that are consistent with this division.

39 (B) Medication donated under this division shall not be
40 transferred by any participating entity more than once, and after

1 it has been transferred, shall be dispensed to an eligible patient,
2 destroyed, or returned to a reverse distributor or licensed waste
3 hauler.

4 (C) Medication transferred pursuant to this paragraph shall be
5 transferred with documentation that identifies the drug name,
6 strength, and quantity of the medication, and the donation facility
7 from where the medication originated shall be identified on
8 medication packaging or in accompanying documentation. The
9 document shall include a statement that the medication may not
10 be transferred to another participating entity and must be handled
11 pursuant to subparagraph (B). A copy of this document shall be
12 kept by the participating entity transferring the medication and the
13 participating entity receiving the medication.

14 (h) Medication that is donated to the repository and distribution
15 program that does not meet the requirements of this division shall
16 not be distributed or transferred under this program and shall be
17 either destroyed or returned to a reverse distributor.—This
18 ~~medication~~ *Donated medication that does not meet the*
19 *requirements of this division* shall not be sold, dispensed, or
20 otherwise transferred to any other entity.

21 (i) Medication donated to the repository and distribution program
22 shall be maintained in the donated packaging units until dispensed
23 to an eligible patient under this program, who presents a valid
24 prescription. When dispensed to an eligible patient under this
25 program, the medication shall be in a new and properly labeled
26 container, specific to the eligible patient and ensuring the privacy
27 of the individuals for whom the medication was initially dispensed.
28 Expired medication shall not be dispensed.

29 (j) Medication donated to the repository and distribution program
30 shall be segregated from the participating entity's other drug stock
31 by physical means, for purposes including, but not limited to,
32 inventory, accounting, and inspection.

33 (k) A participating entity shall keep complete records of the
34 acquisition and disposition of medication donated to, and
35 transferred, dispensed, and destroyed under, the repository and
36 distribution program. These records shall be kept separate from
37 the participating entity's other acquisition and disposition records
38 and shall conform to the Pharmacy Law (Chapter 9 (commencing
39 with Section 4000) of Division 2 of the Business and Professions
40 Code), including being readily retrievable.

1 (l) Local and county protocols established pursuant to this
2 division shall conform to the Pharmacy Law regarding packaging,
3 transporting, storing, and dispensing all medications.

4 (m) County protocols established for packaging, transporting,
5 storing, and dispensing medications that require refrigeration,
6 including, but not limited to, any biological product as defined in
7 Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262),
8 an intravenously injected drug, or an infused drug, shall include
9 specific procedures to ensure that these medications are packaged,
10 transported, stored, and dispensed at appropriate temperatures and
11 in accordance with USP standards and the Pharmacy Law.

12 (n) Notwithstanding any other provision of law, a participating
13 entity shall follow the same procedural drug pedigree requirements
14 for donated drugs as it would follow for drugs purchased from a
15 wholesaler or directly from a drug manufacturer.